

1. A tissue shaping instrument comprising  
a proximal controlling end;  
a distal effector end;  
an elongated portion connecting the distal effector end to the proximal controlling  
5 end, the elongated portion being of sufficient length to enable an operator to access an  
interior of a hollow organ of a subject with the distal effector end while the proximal  
controlling end remains outside of the subject;  
a first tissue engaging device disposed on the distal effector end and operably  
connected to the proximal controlling end, the first tissue engaging device being  
10 structured for releasably engaging at least the inner surface of the hollow organ and for  
manipulating tissue thus engaged;  
a second tissue engaging device also disposed on the distal effector end and  
operably connected to the proximal controlling end, the second tissue engaging device  
being structured for  
15 (a) releasably engaging the interior of the hollow organ, and  
(b) moving relative to the first tissue engaging device,  
wherein the controlling end of the instrument is structured to actuate the tissue  
engaging device.
- 20 2. The tissue shaping instrument of claim 1, wherein the instrument is an  
endoscopic instrument.
3. The tissue shaping instrument of claim 1, further comprising a tissue  
securing device disposed at the distal effector end and operably connected to the  
25 proximal controlling end.
4. The tissue shaping instrument of claim 3, wherein at least one tissue  
fixation device is configured to be loaded into the tissue securing device by a person  
using the device.  
30
5. A tissue shaping instrument comprising

a proximal controlling end;  
a distal effector end;  
an elongated portion connecting the distal effector end to the proximal controlling end, the elongated portion being of sufficient length to enable an operator to access an interior of a hollow organ of a subject with the distal effector end while the proximal controlling end remains outside of the subject;

a first tissue engaging device disposed on the distal effector end and operably connected to the proximal controlling end, the first tissue engaging device being structured for releasably engaging at least the inner surface of the hollow organ and for manipulating tissue thus engaged so as to reconfigure a portion of at least the interior of the hollow organ;

a second tissue engaging device also disposed on the distal effector end and operably connected to the proximal controlling end, the second tissue engaging device being structured for

(a) releasably engaging the interior of the hollow organ and for manipulating tissue thus engaged so as to reconfigure a portion of the interior of at least the interior of the hollow organ,

(b) moving relative to the first tissue engaging device, and

(c) working cooperatively with a tissue securing device; and

a tissue securing device disposed at the distal effector end and operably connected to the proximal controlling end, wherein the tissue securing device is effective for fixing tissue of the hollow organ reconfigured by at least one of the first tissue engaging device and the second tissue engaging device,

wherein the controlling end of the instrument is structured to actuate the tissue engaging device and the tissue securing device.

6. The instrument of claim 5 wherein the instrument is an endoscopic instrument.

7. The tissue shaping instrument of claim 5 wherein either or both the first tissue engaging device and the second tissue engaging device comprises a jawed clamp.

8. The tissue shaping instrument of claim 5 wherein at least one of the first tissue engaging device and the second tissue engaging device comprises a corkscrew-like retractor.

5

9. The tissue shaping instrument of claim 5 wherein the tissue securing device comprises a stapler.

10. The tissue shaping instrument of claim 9 wherein the stapler comprises a one-sided stapler.

11. The tissue shaping instrument of claim 5 wherein the tissue securing device comprises a device structured for delivering at least one biocompatible tissue fixation device into a tissue.

15

12. The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is selected from the group consisting of a staple, a clip, a tack, a rivet, a two-part fastener, a helical fastener, a suture, and a T-bar suture.

20 13. The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a staple.

14. The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a two-part fastener.

25

15. The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a suture.

30 16. The tissue shaping instrument of claim 11 wherein the at least one tissue fixation device is a T-bar suture.

17. The tissue shaping instrument of claim 5 wherein either or both the first tissue engaging device and the second tissue engaging device is non-piercing.

18. The tissue shaping instrument of claim 5 wherein at least part of the elongated portion is flexible.

19. The tissue shaping instrument of claim 5 further comprising a viewing endoscope.

20. The tissue shaping instrument of claim 5 further comprising at least one working channel.

21. The tissue shaping instrument of claim 5 wherein the instrument is sterilized.

15

22. A tissue engaging device comprising  
a proximal controlling end;  
a distal effector end; and  
an elongated portion connecting the distal effector end to the proximal controlling end, the elongated portion being of sufficient length to enable an operator to access an interior of a hollow organ of a subject with the distal effector end while the proximal controlling end remains outside of the subject;

wherein the distal effector end comprises a helix with a sharpened end structured to be reversibly screwed into and out of a tissue brought into in contact with the sharpened end, and

wherein the controlling end of the tissue engaging device is structured to actuate the tissue engaging device.

23. The tissue engaging device of claim 22 wherein the device is an endoscopic device.

24. Apparatus comprising:  
means for transorally engaging a plurality of regions of stomach tissue with a plurality of members from within the stomach, at least one of the members configured to move toward another member to reconfigure tissue, and  
5 means for pulling tissue located between the plurality of regions of tissue prior to engaging the plurality of regions of tissue.

25. The apparatus of claim 24 wherein the plurality of members include a first member having a first securing part configured to engage a first tissue section and a  
10 second member having a second securing part configured to engage a second tissue section.

26. The apparatus of claim 24 wherein the engaging means includes a  
15 corkscrew element.

27. The apparatus of claim 24 wherein the engaging means includes a  
clamping device.

28. The apparatus of claim 24 wherein the engaging means includes a suction  
20 device.

29. The apparatus of claim 24 wherein the engaging means includes a  
grasping device.

30. The apparatus of claim 24 further comprising a means for securing the  
25 reconfigured tissue.

31. The apparatus of claim 30 wherein the securing means includes one or more of: a staple, a clip, a tack, a rivet, a two-part fastener, a helical fastener, a suture, a  
30 T-bar suture, and a tissue adhesive.

32. The apparatus of claim 30 wherein the securing means is biocompatible.

33. The apparatus of claim 30 wherein the securing means is non-resorbable.

5 34. Apparatus comprising:

an elongated member configured for transoral placement in the stomach and having a distal region including first and second movable members configured to be moved toward one another to reconfigure stomach tissue, the distal region being steerable as a unit, and

10 means for deploying an implant from at least one of the members to secure the reconfigured tissue.

35. The apparatus of claim 34 wherein the first movable member includes a first securing part configured to engage a first tissue section and the second movable  
15 member includes a second securing part configured to engage a second tissue section.

36. The apparatus of claim 34 wherein the elongated member includes a corkscrew element.

20 37. The apparatus of claim 34 wherein the elongated member includes a clamping device.

38. The apparatus of claim 34 wherein the elongated member includes a suction device.

25

39. The apparatus of claim 34 wherein the elongated member includes a grasping device.

40. The apparatus of claim 34 wherein the deploying means includes a distal  
30 end effector configured to contact the reconfigured stomach tissue.

41. The apparatus of claim 40 wherein the distal end effector includes at least one tissue fixation device.

42. The apparatus of claim 41 wherein the distal end effector is configured for  
5 application of the at least one tissue fixation device into the reconfigured stomach tissue.

43. The apparatus of claim 40 further comprising a means for controlling the distal end effector.

10 44. The apparatus of claim 43 wherein the controlling means is disposed at a proximal end of the apparatus and is operatively connected to the distal end effector.